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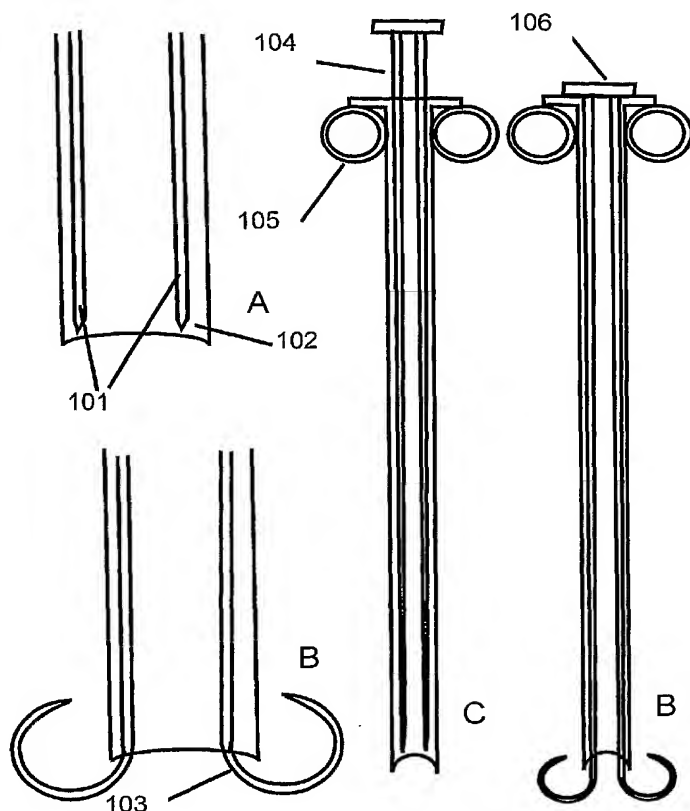
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[Continued on next page]

(54) Title: VASCULAR OPENING EDGE EVERSION METHODS AND APPARATUSES



(57) Abstract: Tissue eversion apparatuses and methods suitable for use, as examples, with vascular closure devices. The tissue eversion apparatuses comprise a tissue engaging element, disposed within a delivery sheath. The delivery sheath protects the tissue engaging element and the surrounding tissue during use. The tissue engaging element can extend from the sheath and engage the tissue near an aperture in a tissue wall. Motion of the tissue engaging element away from the tissue can urge the tissue wall near the aperture to evert from the tissue wall, allowing, as examples, aperture closure apparatuses and methods to be conveniently employed.



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**Vascular Opening Edge Eversion Methods and Apparatuses****Technical Field**

[0001] The present invention relates to methods and apparatuses for closing punctures and apertures in human and animal tissue and to methods and apparatuses for inserting such an apparatus into such tissue to perform such closure functions.

**Background Art**

[0002] This application is related to U.S. provisional application 60/711,279, filed 8/24/2005, and to U.S. utility application 11/316,775, filed 12/23/2005, each of which is incorporated herein by reference. During angiography and related procedures, catheters are inserted through an incision or puncture in the skin and underlying tissues to access an artery or vein, typically in the groin, neck, or subclavian areas of a patient. The catheter can be inserted through a puncture in the blood vessel and guided to the desired site to perform interventional procedures such as angiography, angioplasty, plaque removal, and infusion of a therapeutic substance. After the procedure is completed and the catheter is removed from the patient, the access hole must be closed to prevent massive hemorrhage. This is conventionally achieved by applying pressure over the blood vessel manually and then by applying a pressure bandage, compressive weight, or clamp device. With conventional methods, the rate of post-puncture hemorrhage is high, which causes considerable complications. This complication is exacerbated by the concomitant use of anticoagulant medications such as heparin or warfarin and by antiplatelet drugs, which are commonly used to treat vascular disease.

[0003] Sutures have been used to close access puncture wounds in blood vessels. US05613974 describes a device and method for applying sutures to a vascular puncture. US2004/0093027A1 describes barbed suture-like material that apposes the puncture site. US 2005/0121042 A1 describes a device and method for applying suture to a vascular puncture. Difficulties with these methods include the large number of steps necessary to deploy the needles, capture the suture, withdraw the suture, tie the knot, and cut the suture. In addition, the hole in the blood vessel is often widened by insertion of the instrument, and the suture remains intravascularly on the endothelial surface, and thus can be a nidus for thrombus or intravascular mural hyperplasia with later spontaneous and catastrophic closure of the vessel.

[0004] Extravascular plugs have also been proposed for closure of vascular punctures. US05254105 and US05330445 describe an extravascular plug which is slid down the external surface of the catheter or introducer and is placed into the puncture site in this manner. US05643318 relates to a similar device that has its own vessel locator device. US22022822A1 and US2004/0158287A1 describe an extravascular plug that is delivered with a specialized system. US24215232A1 describes an extravascular plug with an intravascular anchor set with a sheath with a detection port. US2005/0085855A1 describes an extravascular collagen plug, held in place with an intravascular anchor, and a device that locks over a piece of suture. US05906631 describes a plug made of hydrophilic material. US06126675 describes an intravascular anchor and a bioabsorbable extravascular plug. US06623509 describes a bioabsorbable plug. US06296657 and US06743195 describe an inflatable balloon that puts pressure on the puncture site. US06569185 describes an injectable vascular plug. US06663655 describes a plug that screws in the puncture tract. US2004/0143290 A1 describes a combination of an intraluminal balloon and injectable sealant. Disadvantages to these methods are related to the high likelihood of thrombosis associated with the

intravascular plug or anchor, and the presence of collagen or other bioabsorbable materials which cause inflammation, activate the clotting cascade, and increase the likelihood of thrombosis, which, in an arterial system, is catastrophic.

[0005] Vascular patches have also been used for repairing blood vessels, but usually only for large areas of damage. US05100422 describes a vascular patch that is sutured to the external surface of the damaged blood vessel. US05100422 describes a vascular patch achieved by instilled adhesives and the device for doing such. These are generally impractical for catheter-based methods. US06248124 and US05507744 describe devices and methods that use electrocautery for sealing vascular punctures. This also requires a complicated device, and perforation and thrombosis are very real possibilities.

[0006] Vascular clips or staples delivered through a catheter device have also been proposed. These devices have penetrating members that bring the edges of the tissue together. US06695867 describes a clip or staple that is delivered by a specialized device. US06749622 describes a number of different clips with sharpened barbs or ends that include both intra- and extravascular portions, made of metal with memory characteristics. US05861005 describes an arterial staple that is delivered with a specialized device. US05919207 describes a stapling system based on long hooked wires that appose the surfaces, with a small staple gun to close the lesion. US06022372 describes a similar staple gun. US06296657, US06663655, and US06749621 describe a clip that is external to the vessel, but clips the two sides of the puncture together, and a device for achieving such. US 5782861 and US 5964782 describe clip devices composed of two or more prongs or hooks that, depending on the direction of the prongs, can clip together the puncture site from the intra- or extravascular position, through the use of a collar which forces the prongs together or other mechanisms. These clip devices are composed of thick semi-rigid material, and can be placed only with a specialized instruments, and because of the rigidity have great potential to injure or cut the blood vessel. Disadvantages of these clip devices in general include difficulty in retrieving the device if misplaced, excessive manipulation required, the thickness of the clip material which tends to cut or shear the blood vessel, the large forces that must be used to curve the staples and fix the clips, the increased possibility of tearing the blood vessel, and the general lack of control of the forces being applied to the blood vessel.

[0007] Accordingly, there is a need for methods and apparatuses that are suitable for closure of vascular punctures or other openings, and that do not suffer from the drawbacks of conventional approaches.

#### **Disclosure of Invention**

[0008] The present invention provides methods and apparatuses that are suitable for closure of vascular punctures or other openings, and that do not suffer from the drawbacks of conventional approaches.

[0009] An apparatus according to the present invention comprises a tool that can be inserted through a puncture wound in a blood vessel, opens within the blood vessel by the extension of multiple members, the members engage and/or penetrate the vessel wall from the intraluminal side of the blood vessel, the members bring the vessel wall into apposition by the combination of traction and the geometric shape of the members, the member can the blood vessel so that a closure device can be inserted over the apposition/eversion device, and a closure device (which could be an external suture or external clip) placed on the outside of the blood vessel where it seizes and engages the everted edges of the puncture wound as the members prevent the blood vessel wound edges from moving, and finally, removing the wound eversion device or detaching the wound eversion device leaving the closure device proximal to everted wound edges.

[0010] The present invention also comprises methods of using devices according to the present invention, and methods for bring aperture edges into apposition using devices such as those described herein.

[0011] Devices according to the present invention can utilize a contractible or expandable material, for example with memory characteristics, that allow the members of the device to open and engaged spontaneously on a puncture wound of a blood vessel. Members of such devices can have textured gripping surfaces, tissue hooks, or penetrators, to seize the vessel wall and stabilize the device. Such devices can use the spontaneous opening and closing characteristics to seize the edges of the puncture site, and close them, resulting in a complete vascular closure. Such devices can be kept in a contracted or expanded state (high energy state of a memory material) by a delivery sheath and assume its functional, closing form (low energy state of a memory material) when pushed off a delivery sheath.

#### **Brief Description of Drawings**

[0012] The invention is explained by using embodiment examples and corresponding drawings, which are incorporated into and form part of the specification.

Figure 1(a,b) is a schematic illustration of an puncture wound eversion-retraction device according to the present invention.

Figure 2(a,b) is a schematic illustration of a puncture wound eversion-retraction according to the present invention.

Figure 3(a,b) is a schematic illustration of a puncture wound eversion-retraction according to the present invention.

Figure 4(a,b,c) is a schematic illustration of a puncture wound eversion-retraction according to the present invention.

Figure 5(a,b) is a schematic illustration of a puncture wound eversion-retraction according to the present invention.

Figure 6(a,b) is a schematic illustration of a puncture wound eversion-retraction according to the present invention.

Figure 7(a,b,c) is a schematic illustration of eversion and retraction of the edges of a tissue opening using a device according to the present invention.

Figure 8(a,b,c,d,e,f,g) is a schematic illustration of steps in a method of closing a tissue opening according to the present invention.

Figure 9(a,b,c,d,e,f) is a schematic illustration of steps in a method of closing a tissue opening according to the present invention.

#### **Modes for Carrying Out the Invention, and Industrial Applicability**

[0013] The present invention provides apparatuses and methods for closing a vascular puncture wound or any tissue aperture, for example those resulting from the insertion of a vascular catheter or surgical instrument, trauma or disease. The present invention embraces both apparatuses and methods for closing tissue openings such as vascular punctures. Devices according to the present invention can be inserted in a vascular sheath, the sheath removed or pulled back, a closure device placed over the everter device, the everted device activated by extending the graspers within the blood vessel, the graspers pulled up against and penetrate the vascular vessel wall, the wound edges everted, apposed, and brought up into the closure

device, and finally the everted wound edges closed distal to the graspers by the means of an extravascular clip, extravascular suture, extravascular glue or patch, extravascular heat coagulation, or by staples or sutures that are placed through the lips of the everted wound edges. This behavior can be provided by forming at least a portion of the grasping device of a memory metal or material. The stress free state corresponds to the state at which the apparatus has closed upon the everted edges of a puncture wound of a blood vessel, and the stressed state is when the device is open and seated on the delivery sheath. Example embodiments of tissue closure apposition devices according to the present invention are shown in Figures 1, 2, 3, and 4. The descriptions may refer to "vessels" for convenience; the present invention is applicable to facilitate closure of various types of tissue openings.

[0014] Figure 1(a,b,c,d) is a schematic illustration of an puncture wound everter device. Figure 1a is a lateral view cutaway of a puncture wound everter device in the closed state (high energy state). A plurality of grasping members 101 (generally a minimum of two members, or otherwise grasping tissue at at least two locations) in the retracted state, and a sheath 102 contains grasping members. This sheath can accommodate a guidewire, or in another embodiment can be inserted through a sheath or a closure device and used like a guidewire. Figure 1b is a lateral view of the same device in the extended or opened state (low energy state), where the grasping members 103 are extended, and curl up and engage and/or pierce the blood vessel wall. Figure 1c is a lateral view of the everting device in the retracted state with a plunger mechanism 104 to extend the grasping members and finger flanges or rests 105 to control the device. Figure 1d is the same device with the grasping members extended by pushing a plunger mechanism 106.

[0015] In Figure 1 the everter device can be placed into the puncture wound by means of a guidewire that can be accommodated within the sheath 102 in which cases the everter device is placed over the guidewire and pushed through the puncture wound into the blood vessel. The closure device is then placed over the everter device and the terminal end brought up against the exterior blood vessel wall. The everter members are then extended and the device pulled up against the blood vessel wall, and the everted wound edges retracted within and held within the closure device, after which the guidewire is removed, the closure mechanism applied by the closure device causing the wound edges to be closed distally to the everting members. At this point the everter members are retracted and both the closure device and everter device removed, leaving the closure mechanism in place on the external surface of the blood vessel.

[0016] Alternatively, in Figure 1 the everter device can be placed into the puncture wound by means of a sheath that can accommodate the everter device internally. The everter device sheath 102 is placed within the operating sheath and pushed through the existing sheath into the puncture wound and into the internal lumen of the blood vessel. The operator sheath is then removed and the closure device is then placed over the everter device with the everter device sheath being used as a guidewire. The terminal end of the closure device is brought up against the exterior blood vessel wall. The everter members of the everter device are then extended, the device pulled up against the blood vessel wall, the everter members penetrating and seizing the blood vessel wall, the everted device being partially retracted, and the everted wound edges being retracted within and held within the closure device. The closure mechanism is then applied by the closure device causing the everted wound edges to be closed distally to the everting grasping members. At this point the everter members are retracted and both the closure device and everter device removed, leaving the closure mechanism in place on the external surface of the blood vessel.

[0017] Figure 1 presents for illustration purposes 2 active members; the device can comprise as few as two active members (or one, if it grasps the tissue at multiple locations), but can include any plurality, and as many as are practical within applicable design considerations. The tissue engagement features, shown as sharp hook-like portions of the active members in the figure, can comprise textured portions or attachments, mating portions with apposing feet, penetrating devices, hooks, teeth, or other adaptations to allow firm grip of the tissue. The members can comprise memory materials to fit within the delivery sheath, to assume a lower profile when delivered, and expanded and engage the vessel wall when extended.

[0018] Figure 2 (a,b,c) demonstrates an example of how a puncture wound everter device according to the present invention can be used. Figure 2a is a lateral cutaway view of the everter device after insertion into the blood vessel where 201 is the everter device sheath, 202 is the retracted (high energy state) grasping member, 203 is the proximal vessel wall; 204 is the guidewire, and 205 is the distal vessel wall. Figure 2b demonstrates the everter device with the grasping members extended where Figure 2b-6 is the extended grasping member, and Figure 207 is the grasping member penetrating the proximal vessel wall. Figure 2c show the everter device with traction, where 208 is the everter device pulled proximally towards the operator, which enlongates, everts, apposes and hold the vessel wall 209, so that a closure device can be placed on the neck of the everted wound margins 210.

[0019] Figure 3 (a,b,c,d) demonstrates how an everter device according to the present invention can be used to apply an extravascular clip or staple. Figure 3a is a lateral cutaway view, where 301 is expulsion portion of the closure devices, 302 is the extravascular clip or staple, and 303 is the extravascular clip or staple delivery sheath. Figure 3b is a view of the clip 304 being delivered onto the neck of the everted wound edges, closing the wound 305. Figure 3c demonstrates the everter device 307 with the members retracted, leaving the clip or staple closed over the guidewire 308. Figure 3d demonstrates the clip or staple left in situ, with the clip 309 left in place, completely closing the puncture wound edges 310.

[0020] Figure 4 (a,b,c,d,e,f,g) is a demonstration of a method to insert a closure device, in this case an extravascular suture. Figure 4a is a lateral view where the gripper sheath 401 is placed over the guidewire 404, so that the distal edge of the sheath has been pushed internally relative to the proximal blood vessel wall 403. The gripper members 402 have not been extended. In Figure 4b the gripper tines 4b-6 are extended penetrating or gripping the proximal blood vessel wall 407. In Figure 4c traction is then placed on the gripper sheath and members 408, which pull and evert the wound edges 409. In Figure 4d the suture introducer sheath 410 is placed over the gripper sheath, and the suture 411 is tightened by pulling on the suture drawstring contained in 412. Figure 4e the suture is then completely closed around the guidewire 414, closing the puncture. In Figure 4f the gripper members 415 are retracted within the everter gripper sheath, and the suture loop 416 is cut. In Figure 4g, if there is no bleeding, the guidewire is removed leaving 417 an external suture closure of the blood vessel puncture wound.

[0021] Figure 5(a,b,) is another schematic illustration of a puncture wound everter device, similar to that of Figure 1. Figure 5a is a lateral view cutaway of a puncture wound everter device in the closed state (high energy state). 501 are the plurality of grasping members (comprising a minimum of two members) in the retracted state; these are constrained within internal lumen 502, which are held within the everter device sheath. Figure 503 is the sheath that contains grasping members. This sheath can accommodate a guidewire, or in another embodiment can be inserted through a sheath or a closure device and used like a

guidewire. Figure 5b is a lateral view of the same device in the extended or opened state (low energy state), where the grasping members 504 are extended, and curl up and engage and/or pierce the blood vessel wall. This device would otherwise be inserted, operated, and used identically to the embodiment in Figure 1. Figure 5 presents for illustration purposes two active members; the device can comprise as few as two active members, but can include any plurality, and as many as are practical within applicable design considerations. The tissue engagement features, shown as sharp hook-like portions of the active members in the figure, can comprise textured portions or attachments, mating portions with apposing feet, penetrating devices, hooks, teeth, or other adaptations to allow firm grip of the tissue. The members can comprise memory materials to fit within the delivery sheath, to assume a lower profile when delivered, and expanded and engage the vessel wall when extended.

[0022] Figure 6(a,b) is another schematic illustration of a puncture wound everter device, similar to that of Figure 1. Figure 6a is a lateral view cutaway of a puncture wound everter device in the closed state (high energy state). 601 are the plurality of grasping members (comprising a minimum of two members) in the retracted state; these are constrained within internal lumen Figure 602 (or not), which are held within the everter device sheath 603 is the sheath that contains grasping members. In this case the members are extended in a cross-wise function across the sheath, the purpose being that the wound edges are more efficiently and mechanically brought into apposition by the method of retraction. The sheath can accommodate a guidewire, or in another embodiment can be inserted through a sheath or a closure device and used like a guidewire. Figure 6b is a lateral view of the same device in the extended or opened state (low energy state), where the grasping members 604 are extended, and curl up and engage and/or pierce the blood vessel wall. This device would otherwise be inserted, operated, and used identically to the embodiment in Figure 1. Figure 6 presents for illustration purposes two active members; the device can comprise as few as two active members, but can include any plurality, and as many as are practical within applicable design considerations. The tissue engagement features, shown as sharp hook-like portions of the active members in the figure, can comprise textured portions or attachments, mating portions with apposing feet, penetrating devices, hooks, teeth, or other adaptations to allow firm grip of the tissue. The members can comprise memory materials to fit within the delivery sheath, to assume a lower profile when delivered, and expanded and engage the vessel wall when extended.

[0023] Figure 7(a,b,) is another schematic illustration of an puncture wound everter device, similar to that of Figure 1. Figure 7a is a lateral view cutaway of a puncture wound everter device in the closed state (high energy state). Figure 701 are the plurality of grasping members (comprising a minimum of two members) in the retracted state; these are constrained within internal lumen Figure 702 (or not), which are held within the everter device sheath 703 is the sheath that contains grasping members. In this case the members are comprised at a sharp geometric angle. The sheath can accommodate a guidewire, or in another embodiment can be inserted through a sheath or a closure device and used like a guidewire. Figure 7b is a lateral view of the same device in the extended or opened state (low energy state), where the grasping members 704 are extended, and curl up and engage and/or pierce the blood vessel wall. This device would otherwise be inserted, operated, and used identically to the embodiment in Figure 1. Figure 7 presents for illustration purposes two active members; the device can comprise as few as two active members, but can include any plurality, and as many as are practical within applicable design considerations. The tissue



engagement features, shown as sharp hook-like portions of the active members in the figure, can comprise textured portions or attachments, mating portions with apposing feet, penetrating devices, hooks, teeth, or other adaptations to allow firm grip of the tissue. The members can comprise memory materials to fit within the delivery sheath, to assume a lower profile when delivered, and expanded and engage the vessel wall when extended.

[0024] Figure 8(a,b,c,d) is a schematic illustration of a puncture wound everter device. Figure 8a is a lateral view cutaway of a puncture wound everter device in the closed state (high energy state). 801 are the plurality of grasping members (comprising a minimum of two members) in the retracted state; in this case, the members are flexed back within the sheath; and 802 is the sheath that contains grasping members. This sheath can accommodate a guidewire, or in another embodiment can be inserted through a sheath or a closure device and used like a guidewire. Figure 8b is a lateral view of the same device in the retracted or closed states state (low energy state), where the grasping members 803 flexed forward. Figure 8c is a lateral view of the same device in the extended or opened state (low energy state), where the grasping members 804 are extended, and flex up and engage and/or pierce the blood vessel wall which represents the extended form of the devices shown in Figure 8a and Figure 8b. Figure 8d is a lateral view of the same device in the retracted or closed state (high energy state), where the grasping members 805 are retracted, and flexed down which represents the retracted form of the devices shown in Figure 8a and Figure 8b.

[0025] Figure 9(a,b) is another schematic illustration of a puncture wound everter device, similar to that of Figure 1. Figure 9a is a lateral view cutaway of a puncture wound everter device in the partially opened state (half-way to low energy state). 901 are the plurality of grasping members (comprising a minimum of two members) in the partially extended state. Figure 9b is a lateral view of the same device in the fully extended or opened state (low energy state), where the grasping members 902 are extended, and curl towards each other after then have engaged and/or pierced the blood vessel wall. In this case the members when fully extended move towards the midline of the sheath, the purpose being that the wound edges are more efficiently and mechanically brought into apposition during extension and retraction.. This device would otherwise be inserted, operated, and used identically to the embodiments in the prior examples. Figure 9 presents for illustration purposes two active members; the device can comprise as few as two active members, but can include any plurality, and as many as are practical within applicable design considerations. The tissue engagement features, shown as sharp hook-like portions of the active members in the figure, can comprise textured portions or attachments, mating portions with apposing feet, penetrating devices, hooks, teeth, or other adaptations to allow firm grip of the tissue. The members can comprise memory materials to fit within the delivery sheath, to assume a lower profile when delivered, and expanded and engage the vessel wall when extended.

[0026] Figure 10 (a,b,c,d) is a schematic illustration of an example puncture wound everter device. Figure 10a is a lateral view cutaway of a puncture wound everter device in the closed state (high energy state). Figure 1001 are the plurality of grasping members (comprising a minimum of two members) in the retracted state; in this case, the members are closed within an internal lumen 1002 and/or with the sheath 1003. The grasping members are attached to a solid member 1004 which can be a solid or hollow columnar device with an internal lumen for a guidewire, or can be a wire in itself. This sheath can accommodate a guidewire, or in another embodiment can be inserted through a sheath or a closure device and used like a guidewire. Figure

10b is a lateral view of the same device in the extended or open state (low energy state), where the grasping members 1005 are extended into their grasping or extended position. Figure 10c is a lateral view of the everting device in the retracted state with a plunger mechanism 1006 to extend the grasping members and finger flanges or rests 1007 to control the device. Figure 10d is the same device with the grasping members extended by pushing the plunger mechanism 1008.

[0027] Figure 11 (a,b,c,d) is a schematic illustration of an example puncture wound everter device. Figure 11a is a lateral view cutaway of a puncture wound everter device in the closed state (high energy state). 1101 are a plurality of grasping members (comprising a minimum of two members) in the retracted state; in this case, the members can rotate from internally to externally upon each upon an axis moved by a mechanical mechanism 1102 (which could be a flywheel mechanism or gear and groove axel mechanism) all which are closed within an internal lumen 1103 and/or with the sheath 1103. Figure 11b is a lateral view of the same device in the extended or open state, where the grasping members 1104 are extended into their grasping or extended position. Figure 11c is a lateral view of the everting device in the retracted state with a plunger mechanism 1105 to extend the grasping members, and finger flanges or rests 1106 to control the device. Figure 11d is the same device with the grasping members extended by pushing the plunger mechanism 1106.

[0028] Figure 12 (a,b,c,d) is a schematic illustration of an example puncture wound everter device. Figure 12a is a lateral view cutaway of a puncture wound everter device in the closed state (high energy state) that is placed through a puncture wound within the blood vessel. 1201 are internal lumina for the plurality of grasping members 1202 (comprising a minimum of two members) in the retracted state; at least two parallel locator members are also present 1203 in their lumina within the everter device sheath 1204. Figure 12b demonstrates that the grasping members 1205 have not been extended, while the locator members 1206 have been extended. As can be seen, these do not have penetrating surfaces. The locator members are pulled up against the internal edges of the puncture wound, locating the wound margins. In Figure 12c, once the wound margins have been located the grasping members are extended 1207, and these penetrate and grasp the proximal vessel wall. In Figure 12d once the vessel is grasped by the grasping members 1208, the locator members are re-retracted, and the device is then used identically to the other examples.

[0029] Figure 13 (a,b,c,d,e) is a schematic illustration of an example puncture wound everter device. Figure 13a is a lateral view cutaway of a puncture wound everter device in the closed state (high energy state) that is placed through a puncture wound within a blood vessel. 1301 shows the plurality of grasping members (comprising a minimum of two members) in the retracted state within an internal lumen 13a-2 within the everter device sheath 1303. The grasping members 1301 are attached to an internal columnar structure 1304. Figure 13b illustrates the grasping members 1305 extended, by action of the internal columnar structure 1306 being extended. Figure 13c illustrates the grasping members 1308 detached from the columnar structure at the mating area 1307 and expelled independently. Figure 13d is a lateral view of the everting device in the retracted state with a plunger mechanism 1310 to extend the grasping members and finger flanges or rests 1309 to control the device. Figure 13d is the same device with the grasping members extended by pushing the plunger mechanism 1311.

[0030] Figure 14 (a,b,c,d) is a view of another example embodiment of a gripper device with a residing memory gripper being used. In Figure 14a the gripper device sheath 1401 with the residing gripper 1402 with

columnar connector is introduced into the blood vessel 1403 over the guidewire 14a-4. In Figure 14b after introduction, the gripper 1406 is expelled from the sheath, and the gripping members then penetrate and grip 1407 the proximal tissue surrounding the puncture wound. In Figure 14c traction (pulling) is placed on the 1408 gripper sheath and gripper members on the columnar base, everting the wound edges 1409. In Figure 14d a closure device 14010 is placed over the gripper device and closed on the neck of the everted wound edges, closing the wound edges 1411. The gripping device 1412 is detached from the columnar holder and is held in place and prevented from migrating internally by the closure device 1410 and the closure device is prevented from migrating externally by the gripping device 1412. Thus, this is a combination of a clip and a suture.

[0031] Any part of an apparatus according to the present invention can be made from any of a number of suitable materials, or combinations thereof. In some applications, it can be desirable for members to be of radioopaque materials or be coated to be made radioopaque. Members can be made from bioabsorbable polymers or compounds, non-absorbable alloys and compounds including stainless steel, MP35, Nitinol, Nickel-Titanium alloy, Kevlar, nylon polyester acrylic, gold, platinum, tantalum, niobium, molybdenum, rhodium, palladium silver, hafnium, tungsten, iridium. Materials with memory can be useful, where the memory property can provide force for activation of the active members from the open to the closed state. Members can be made in the form of wires, fibers, filaments, small beams, and other extruded, woven, or formed shapes. Examples of suitable materials include piano wire, super elastic memory wire, chromium alloys, alloys of titanium and nickel, and other elastic memory materials. A suitable fabric or coating can be made from a number of suitable materials; in some applications it can be desirable to use flexible polymeric materials with elastomeric properties including polyurethane, polyethylene, polyestenuethane, polyimide, olyethreimide, polycarbonate, polysiloxane, polyvinyls, hydroxyethylmethacrylate, related polymers, co-polymers of these or other polymers, or drug-embedded or drug-eluting polymers to prevent coagulation or intimal hyperplasia (such as Taxol), which can be made radioopaque by markers to addition of appropriate radiopaque materials.

[0032] The particular sizes and equipment discussed above are cited merely to illustrate particular embodiments of the invention. It is contemplated that the use of the invention may involve components having different sizes and characteristics. It is intended that the scope of the invention be defined by the claims appended hereto.

**Claims**

We claim:

- 1) A tissue eversion device, comprising:
  - a) A delivery sheath;
  - b) A tissue engaging element, having a plurality of tissue engagement features, where the tissue engaging element is capable of a first configuration wherein it is contained within the delivery sheath, and a second configuration wherein the tissue engagement features extend beyond the outer surface of the delivery sheath.
- 2) A tissue eversion device as in Claim 1, wherein the tissue engaging element comprises a plurality of elongated members, each having an end adapted to engage tissue, wherein the elongated members reside within the delivery sheath substantially parallel to an axis of the delivery sheath when in the first configuration, and wherein the elongated members curve away from the axis when in the second configuration.
- 3) A tissue eversion device as in Claim 2, wherein the elongated members have sharpened ends.
- 4) A tissue eversion device as in Claim 1, wherein the tissue engaging element comprises metal.
- 5) A tissue eversion device as in Claim 1, wherein the tissue engaging element comprises bioabsorbable polymer, bioabsorbable compound, non-absorbable alloy, non-absorbable compound, stainless steel, MP35, Nitinol, Nickel-Titanium alloy, Kevlar, nylon polyester acrylic, gold, platinum, tantalum, niobium, molybdenum, rhodium, palladium silver, hafnium, tungsten, iridium, artificial muscle, shape memory alloy, or a combination thereof.
- 6) A tissue eversion device as in Claim 1, wherein the tissue engaging element comprises a fixture adapted to attach to a retracting element.
- 7) A tissue eversion device as in Claim 1, wherein the tissue engaging element is moveable relative to the delivery sheath along an axis of the delivery sheath, and wherein motion of the tissue engaging element along the axis past the end of the delivery sheath allows the tissue engaging element to attain the second configuration, and wherein motion of the tissue engaging element into the end of the delivery sheath causes the tissue engaging element to attain the first configuration.
- 8) A method of everting the edges of an aperture in a tissue wall, comprising presenting the delivery sheath of a device as in Claim 1 to the aperture in such proximity thereto that the tissue engaging element will engage the tissue near the edges of the aperture, then extending the tissue engaging element such that the tissue engagement features engage the tissue, then moving the tissue engaging element away from the tissue such that the engaged tissue moves in a direction away from the remainder of the tissue.
- 9) A method of everting the edges of an aperture in a tissue wall, comprising placing the delivery sheath of a device as in Claim 7 at least partially within the aperture, then moving the tissue engaging element at least partially past the end of the sheath and into space behind the tissue wall and engaging the tissue wall, then moving the sheath such that it is not within the aperture, then moving the tissue engaging element away from the wall such that the tissue engaged by the tissue engaging element moves away from the remainder of the tissue.

- 10) A method of closing an aperture in a tissue wall, comprising presenting the delivery sheath of a device as in Claim 1 to the aperture in such proximity thereto that the tissue engaging element will engage the tissue near the edges of the aperture, then extending the tissue engaging element such that the tissue engagement features engage the tissue, then moving the tissue engaging element away from the tissue such that the engaged tissue moves in a direction away from the remainder of the tissue, then applying a tissue closure device to the tissue below the points of engagement by the tissue engagement element.
- 11) A method as in Claim 10, further comprising removing the tissue engaging element after applying the tissue closure device.
- 12) A method of closing an aperture in a tissue wall, comprising placing the delivery sheath of a device as in Claim 7 at least partially within the aperture, then moving the tissue engaging element at least partially past the end of the sheath and into space behind the tissue wall and engaging the tissue wall, then moving the sheath such that it is not within the aperture, then moving the tissue engaging element away from the wall such that the tissue engaged by the tissue engaging element moves away from the remainder of the tissue, then applying a tissue closure device to the tissue below the points of engagement by the tissue engagement element.
- 13) A method as in Claim 12, further comprising separating the tissue engaging element from the delivery sheath.
- 14) A tissue eversion device as in Claim 1, comprising a plurality of tissue engaging elements, and wherein the tissue engaging elements flex or curl outwards relative to the delivery sheath to attain the second configuration.
- 15) A tissue eversion device as in Claim 1, wherein the tissue engaging element can be actuated to attain the second configuration by action of a plunger and flanges mounted with the device.
- 16) A tissue eversion device as in Claim 1, comprising a plurality of tissue engaging elements, and wherein the tissue engaging elements are movably mounted within individual lumens within the delivery sheath.
- 17) A tissue eversion device as in Claim 1, comprising a plurality of tissue engaging elements, and wherein the tissue engaging elements cross the lumen of the delivery sheath when in the second configuration.
- 18) A tissue eversion device as in Claim 1, comprising a plurality of tissue engaging elements, and wherein the tissue engaging elements comprise an abrupt angle to the delivery sheath axis when in the second configuration.
- 19) A tissue eversion device as in Claim 1, comprising a plurality of tissue engaging elements, and wherein the tissue engaging elements are mounted with a columnar element which slidably engages the delivery sheath.
- 20) A tissue eversion device as in Claim 1, further comprising a plurality of localizing elements mounted with the delivery sheath such that the localizing members attain a configuration that locates the delivery sheath relative to tissue before the tissue engaging elements engage tissue.

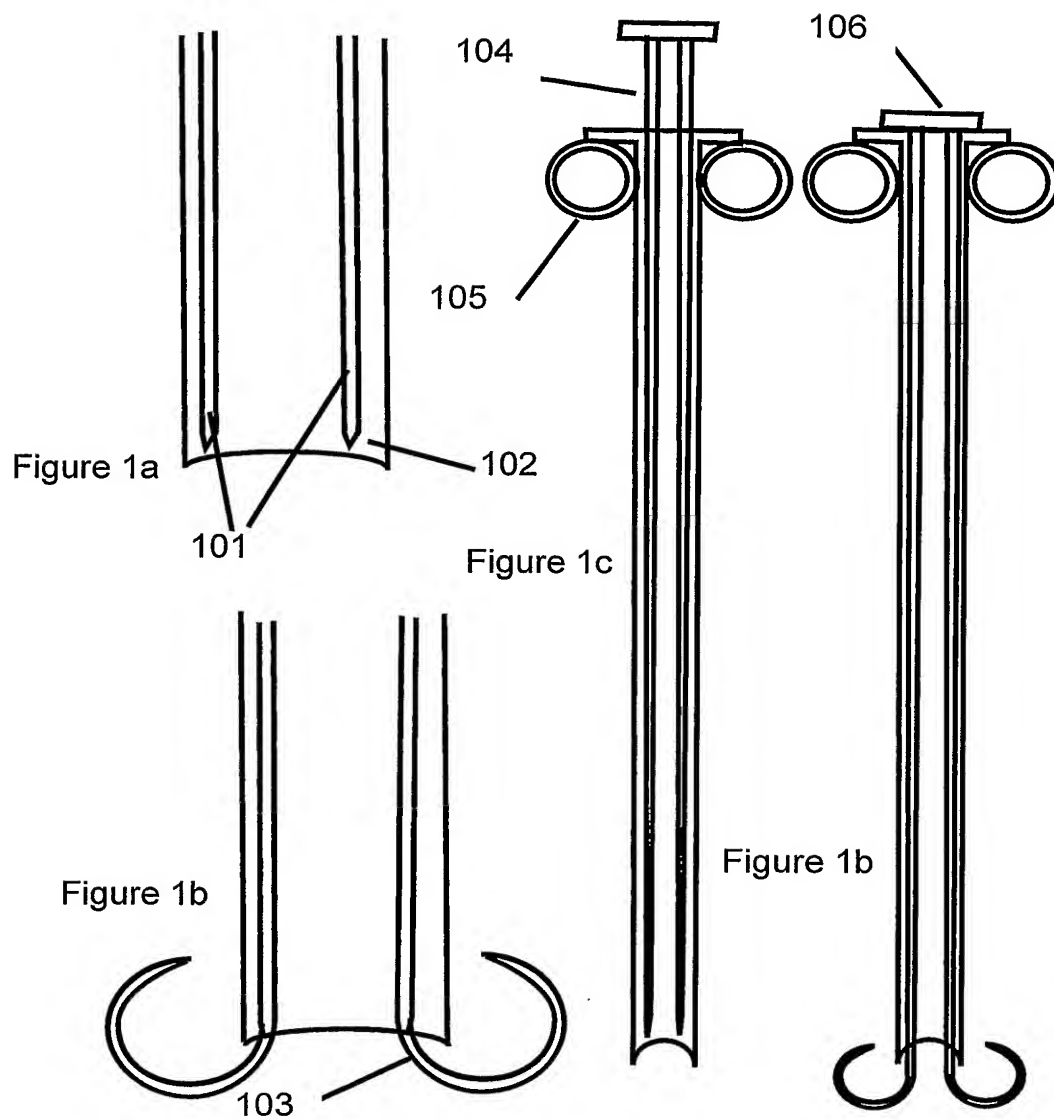


Figure 1

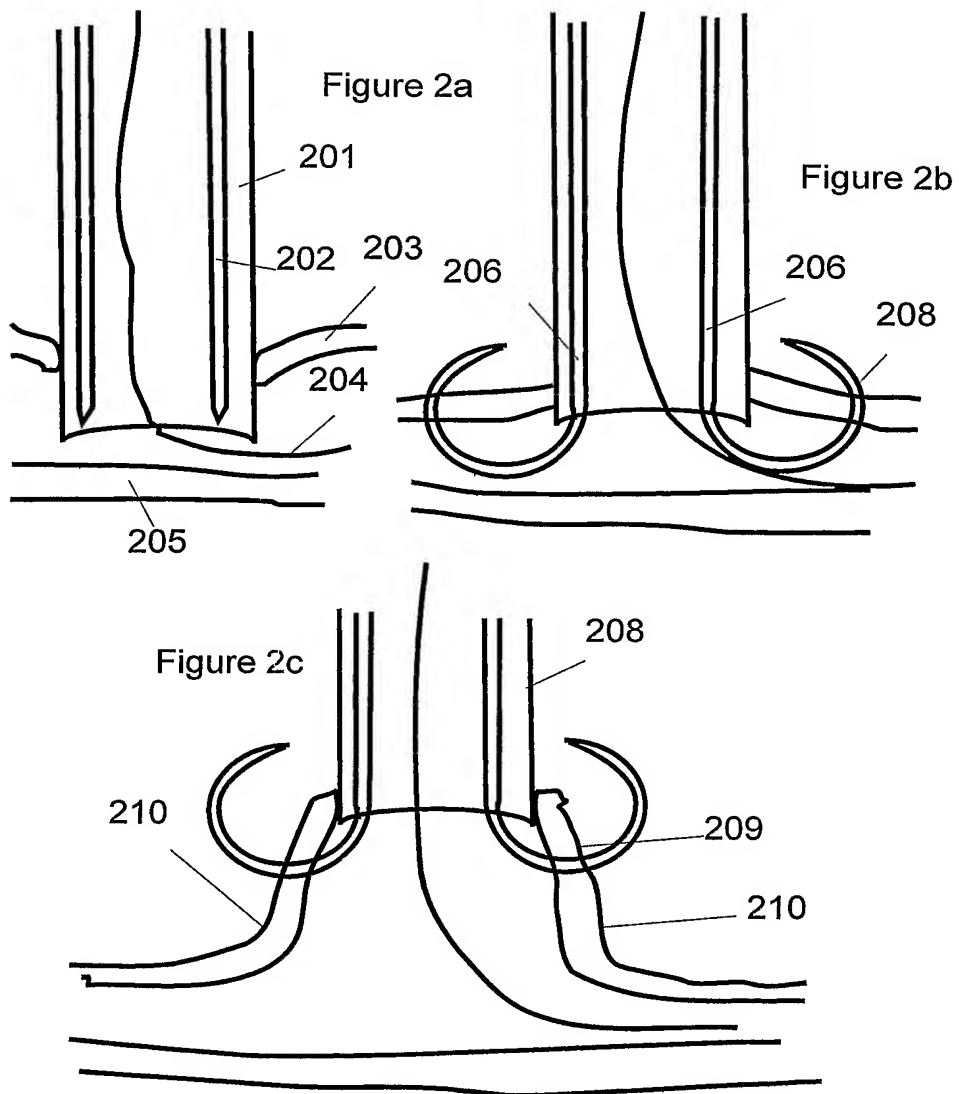


Figure 2

Figure 3a

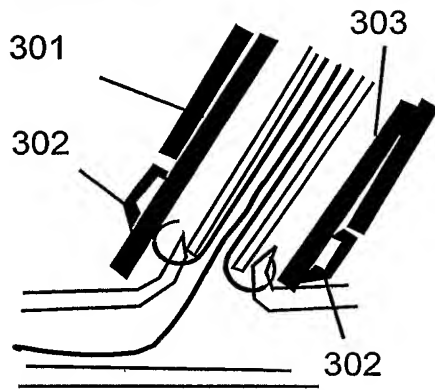


Figure 3b

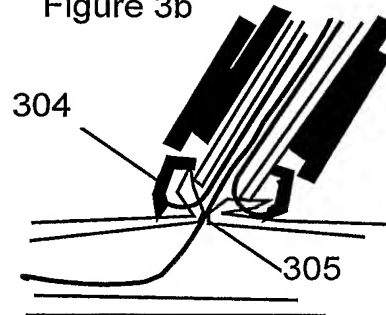


Figure 3d

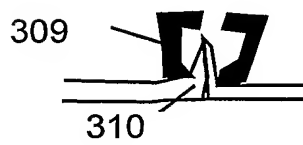


Figure 3c

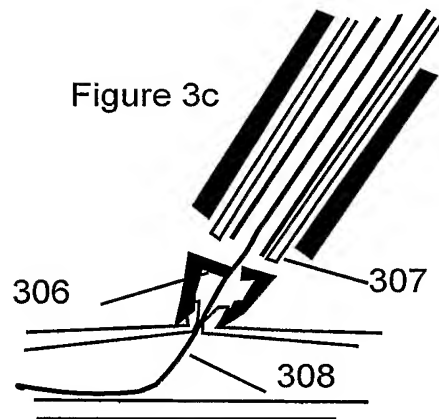


Figure 3



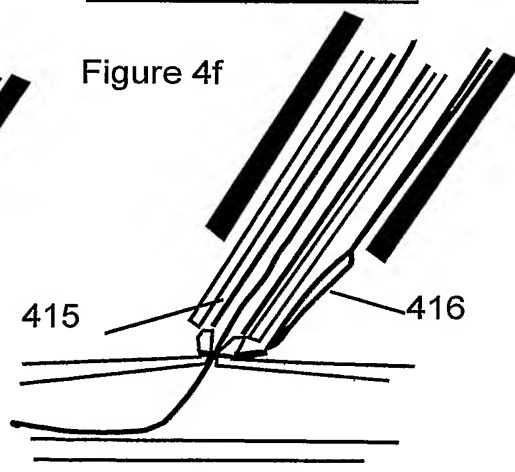
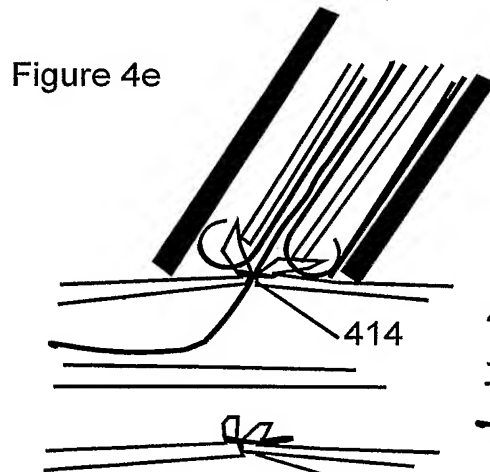
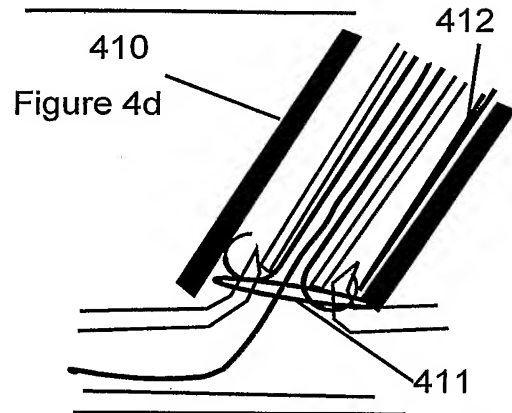
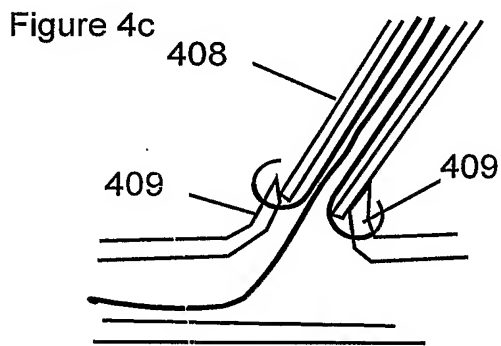
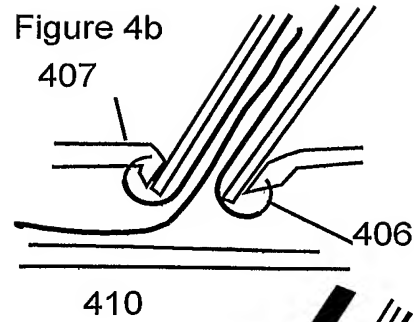
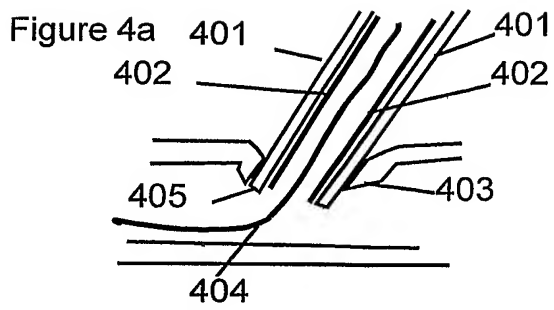
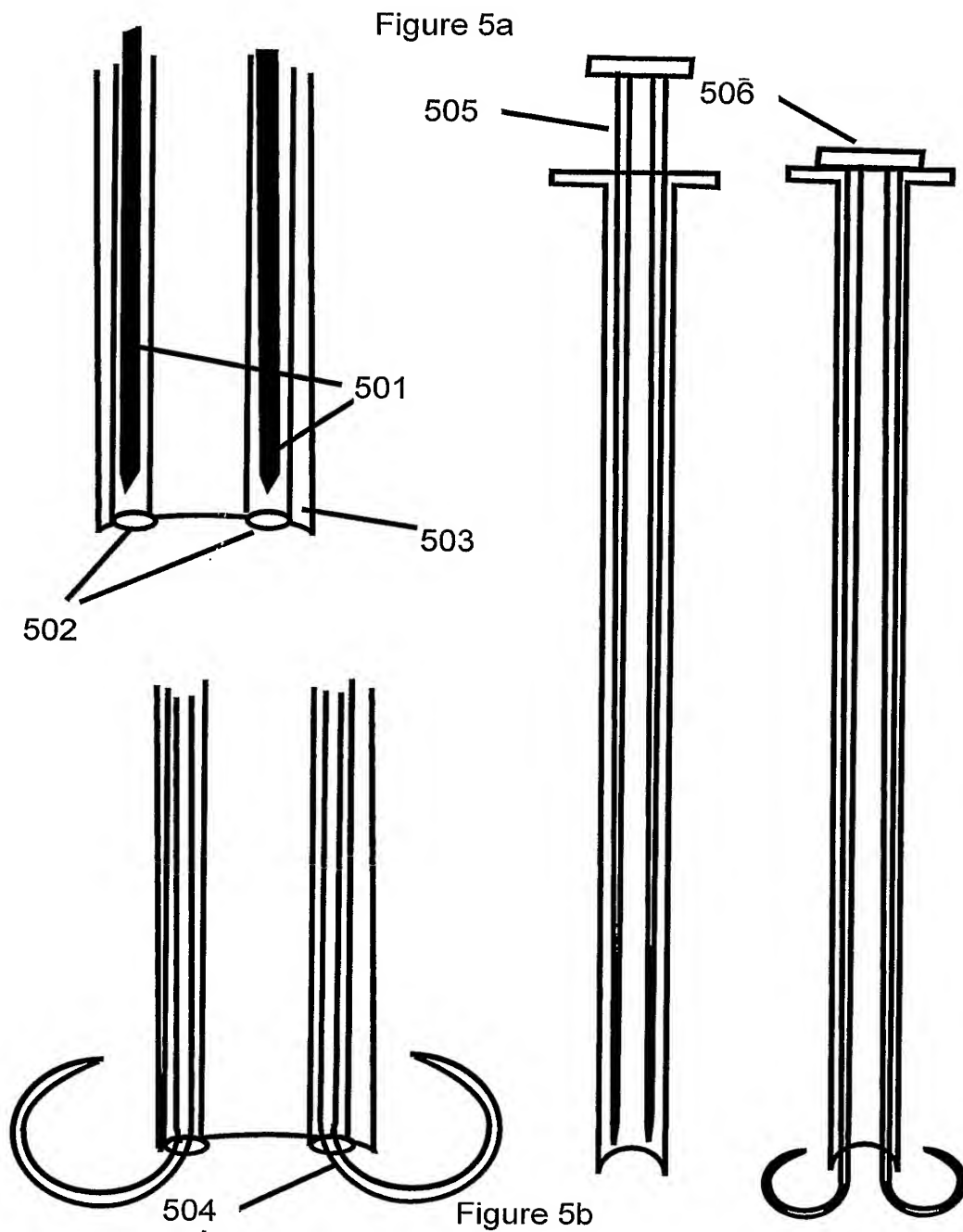


Figure 4



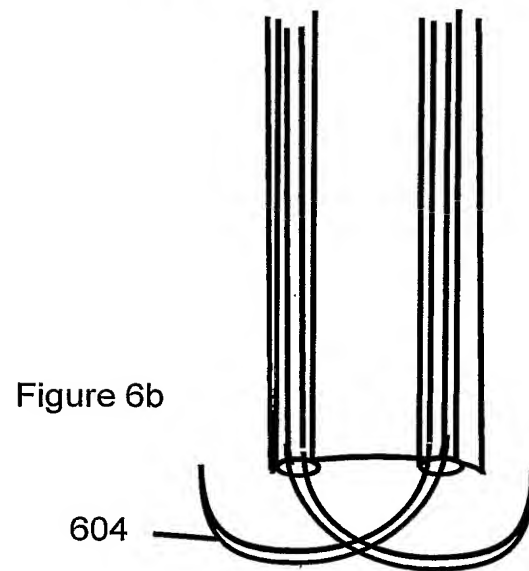
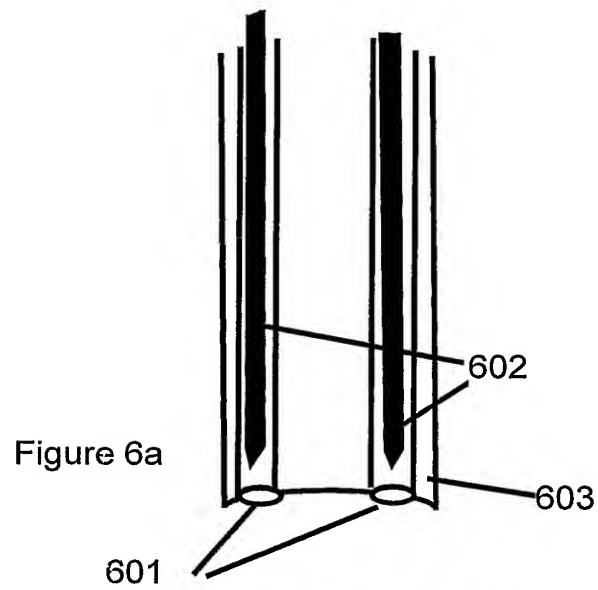


Figure 6

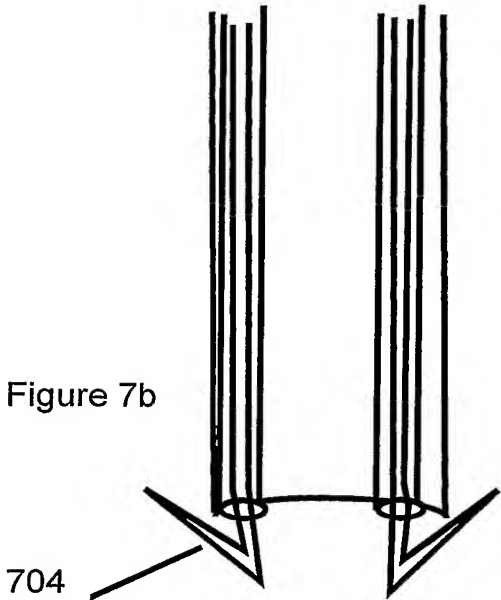
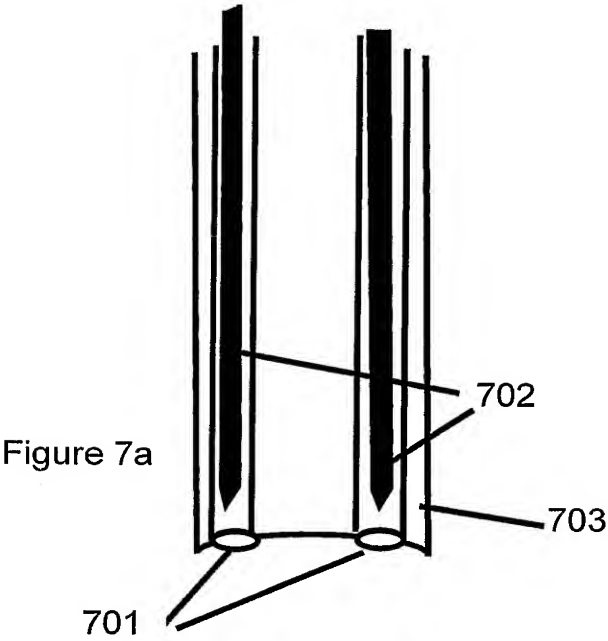


Figure 7

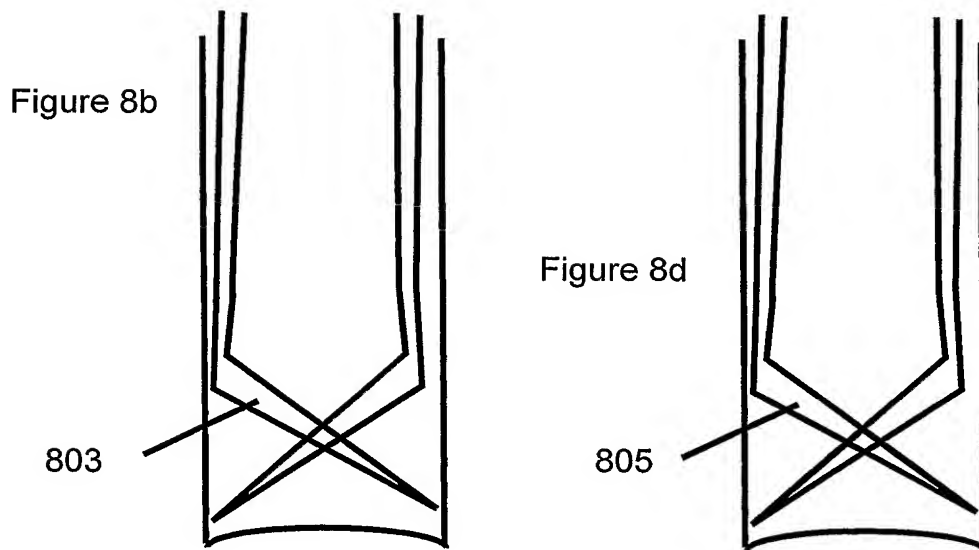
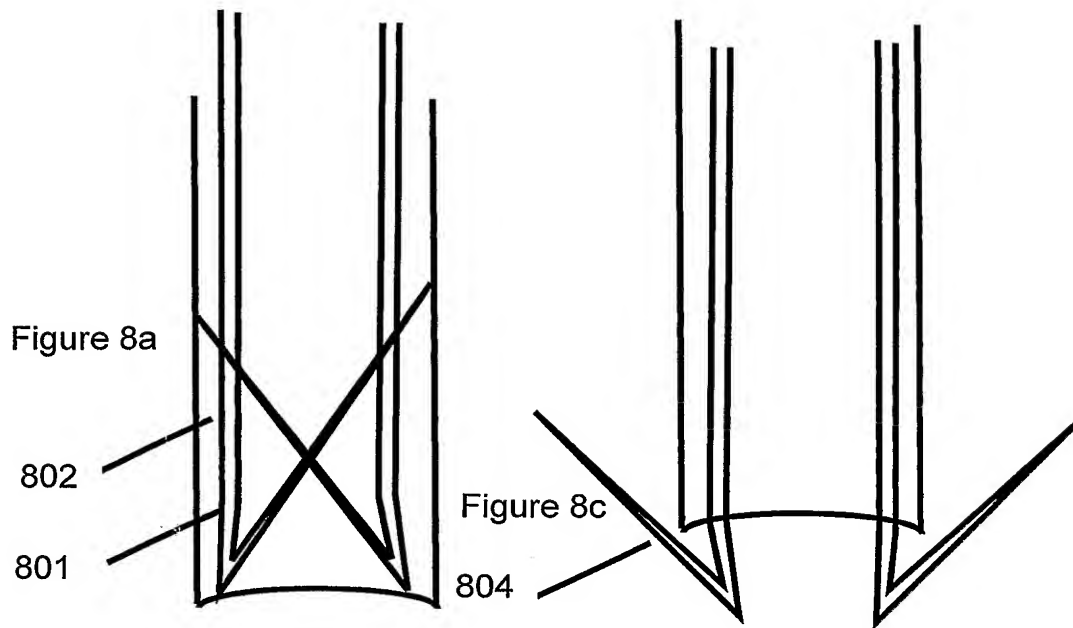


Figure 8

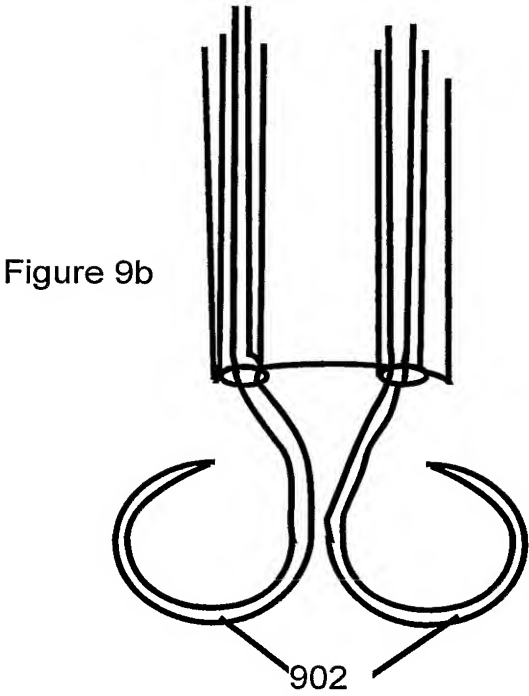
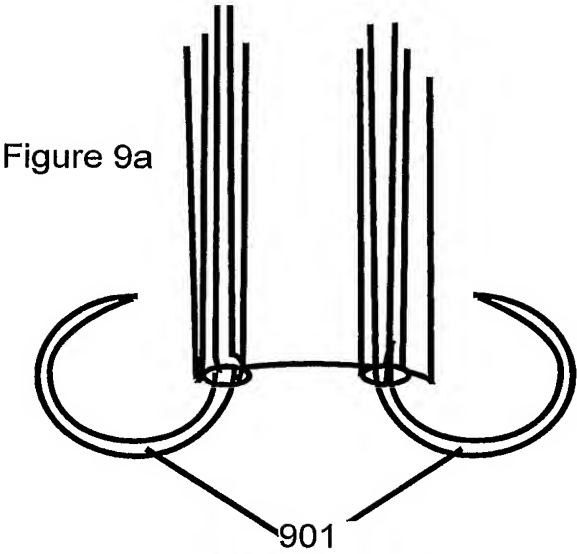
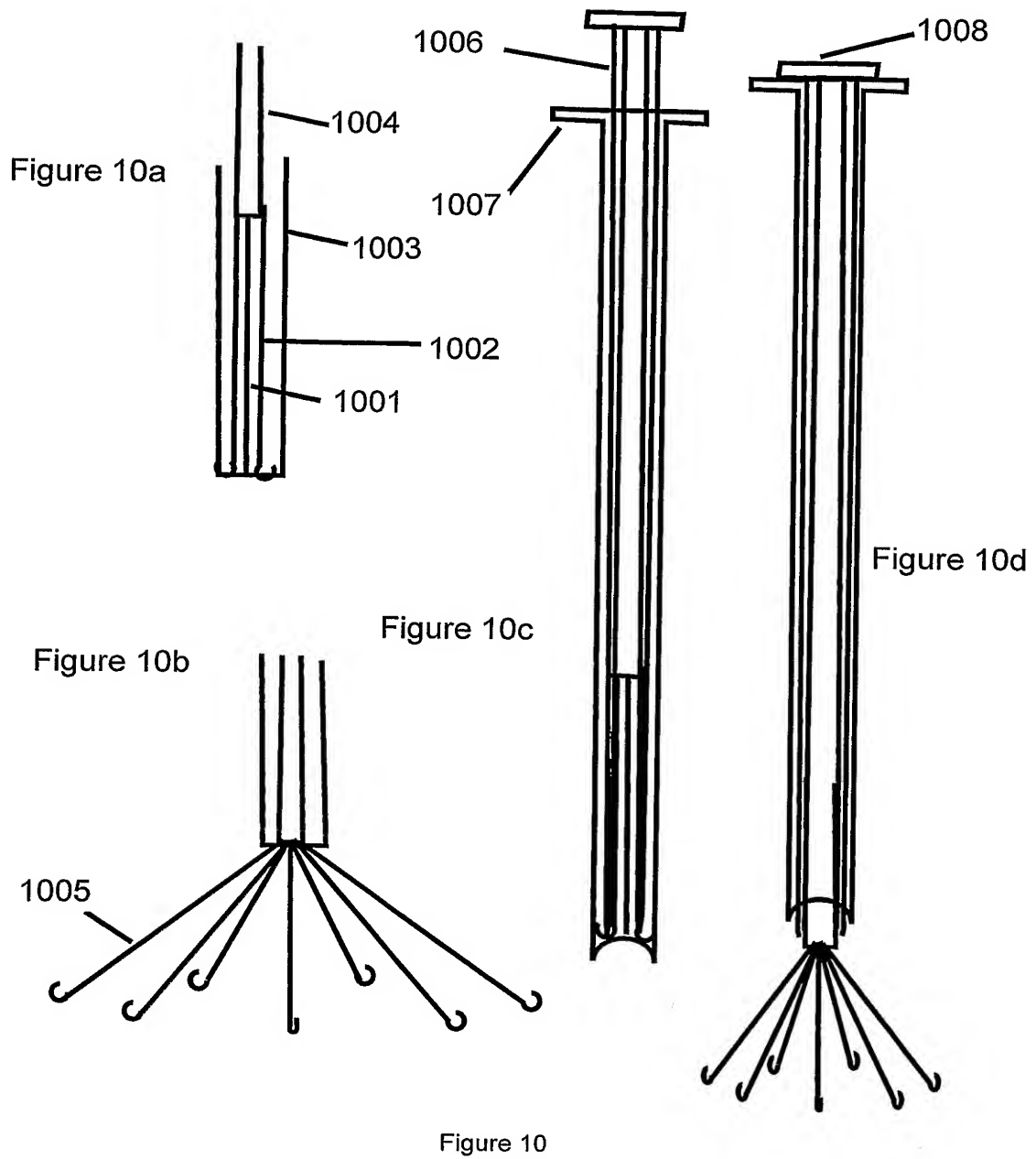


Figure 9



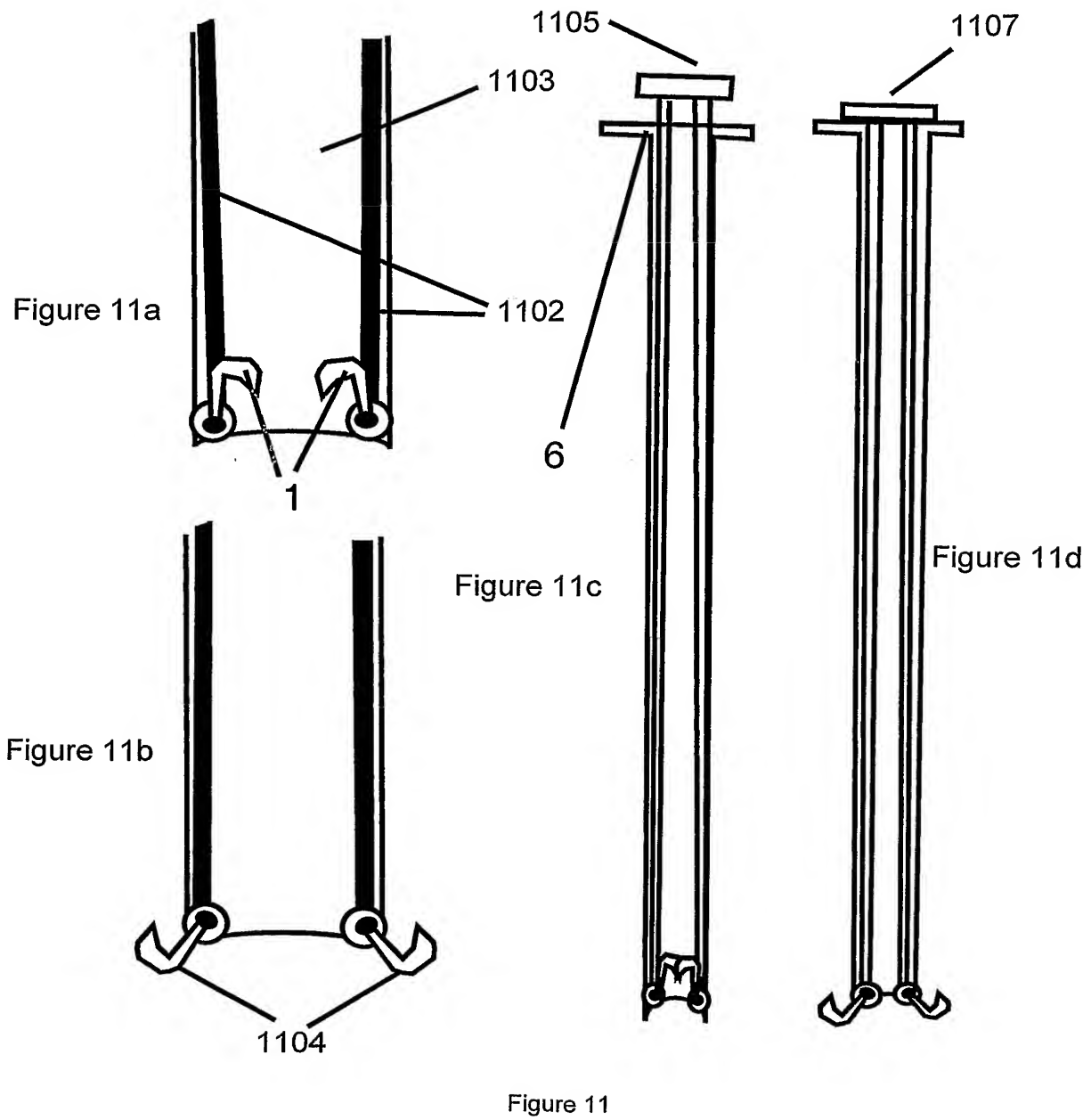




Figure 12a

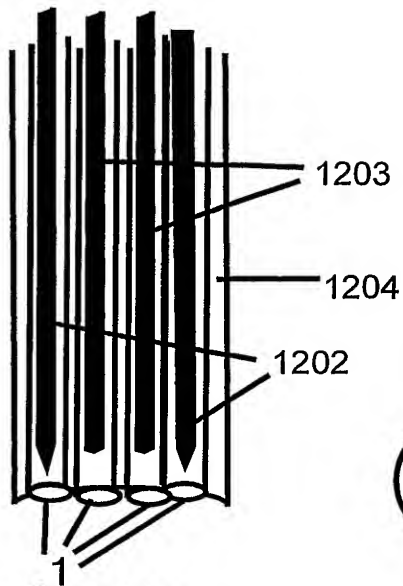


Figure 12c

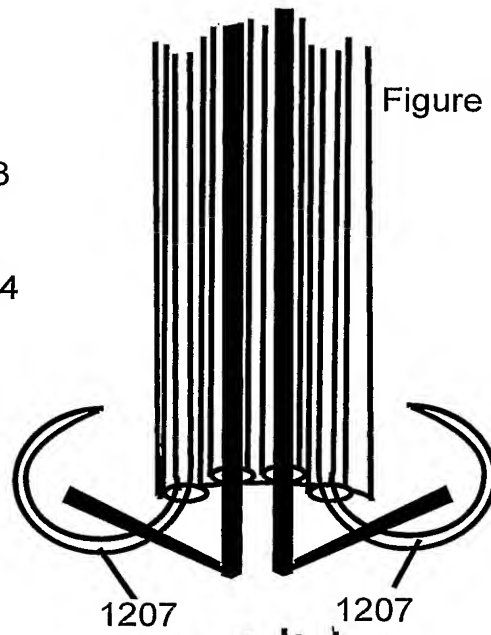


Figure 12b

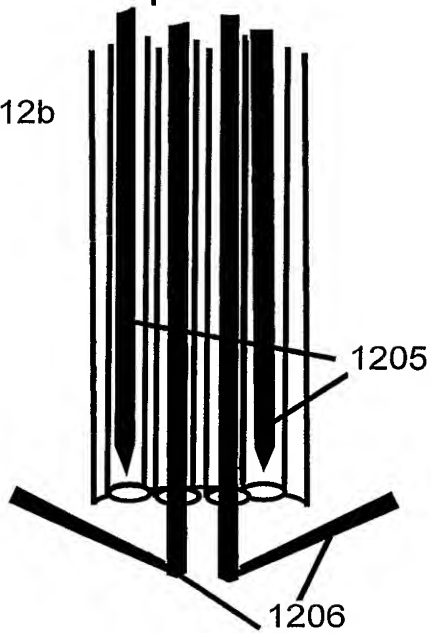


Figure 12d

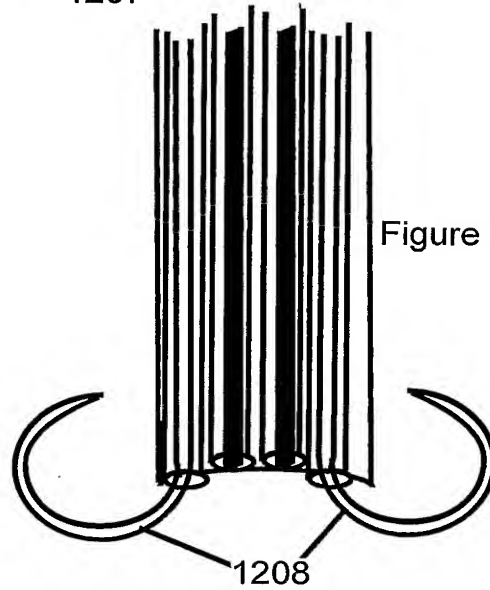
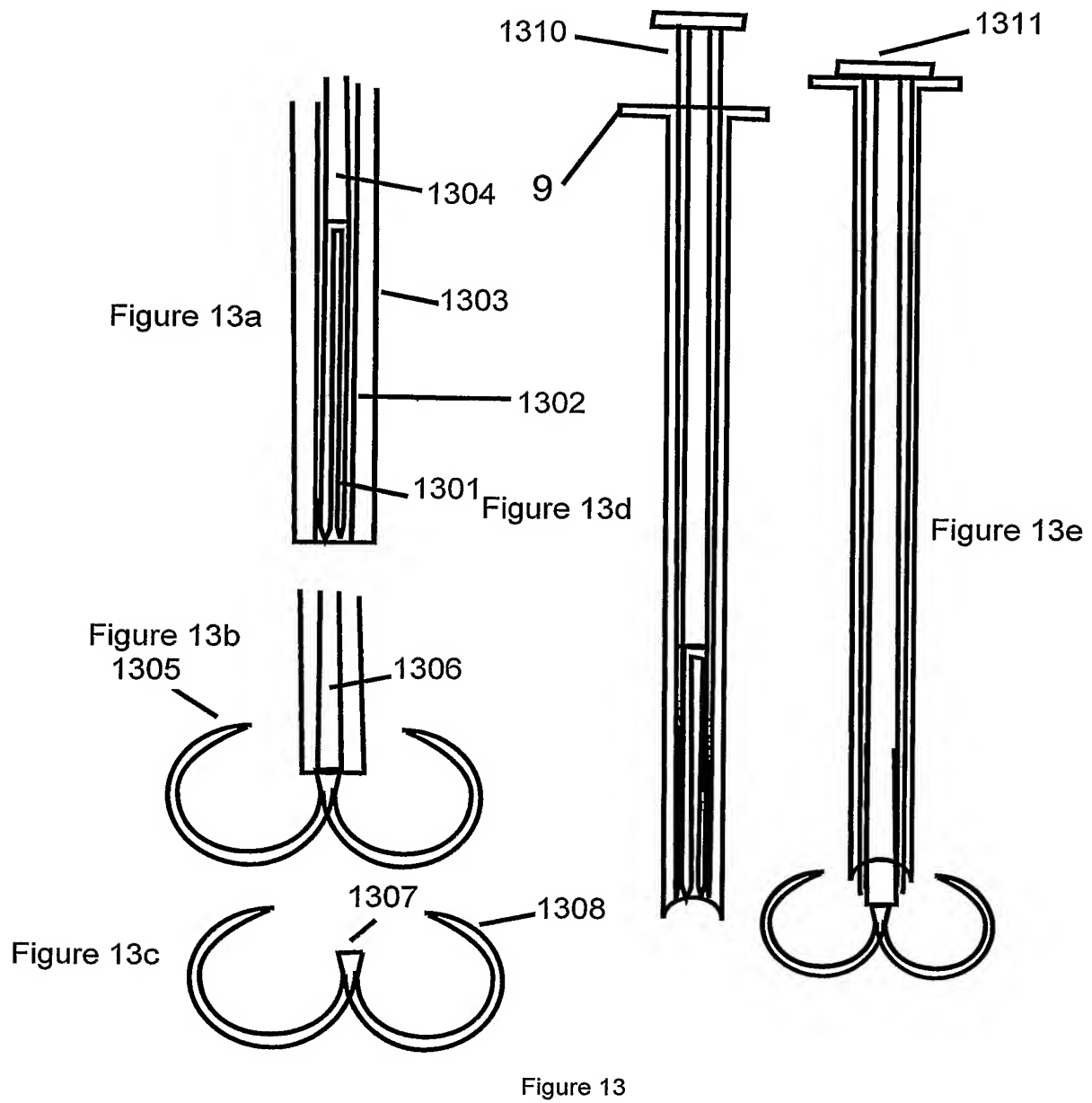


Figure 12



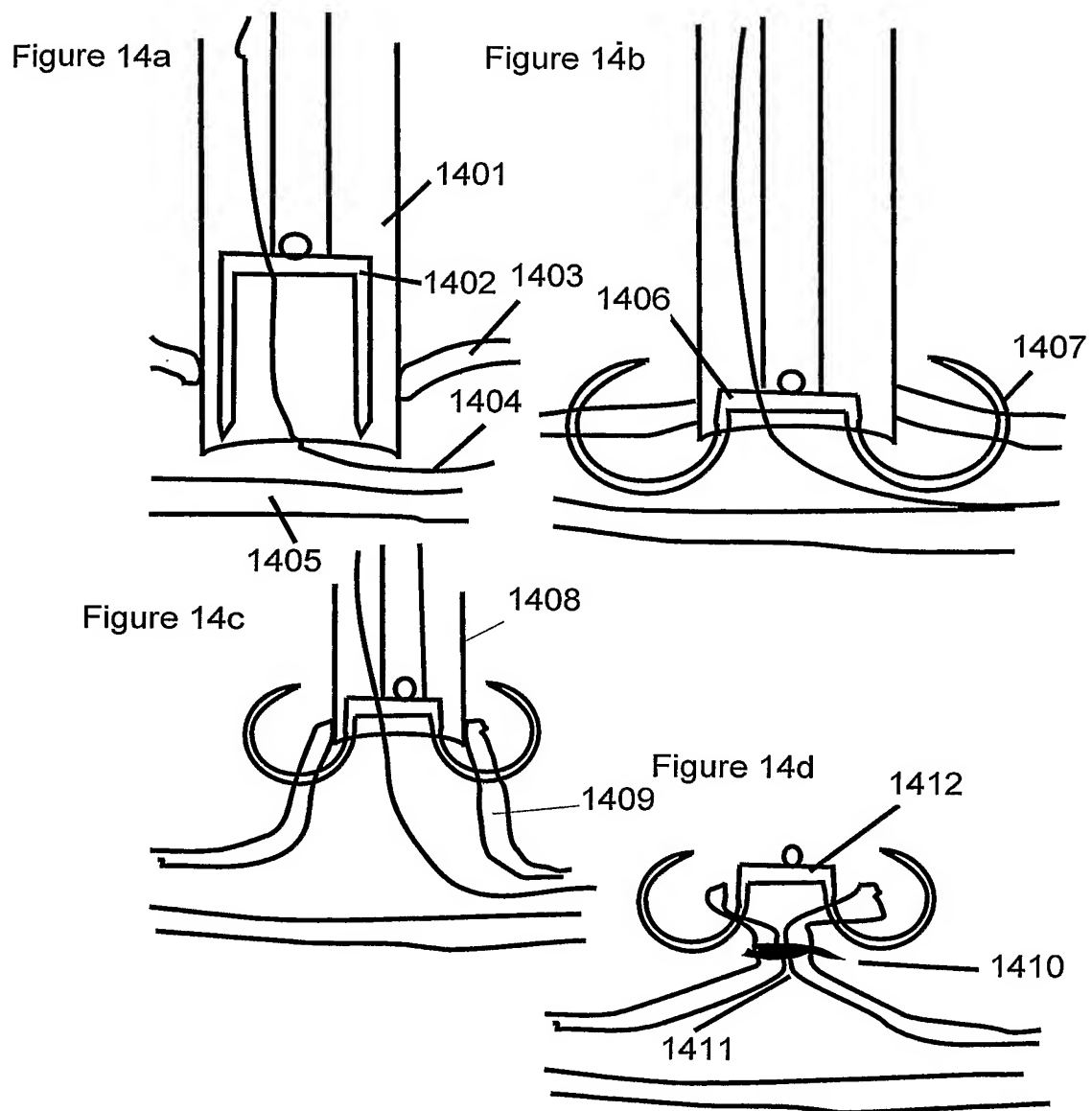


Figure 14

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

## PCT

To: V. Gerald Grafe  
P.O. Box 2689  
Corrales, NM 87048

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT AND  
THE WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference <b>084-06-006</b>	Date of mailing <i>(day/month/year)</i> <b>27 SEP 2007</b>
International application No. <b>PCT/US 06/33032</b>	International filing date <i>(day/month/year)</i> <b>24 August 2006 (24.08.2006)</b>
Applicant <b>SIBBITT, Wilmer L. Jr.</b>	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

**Filing of amendments and statement under Article 19:**  
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

**When?** The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

**Where?** Directly to the International Bureau of WIPO, 34 chemin des Colombettes  
 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

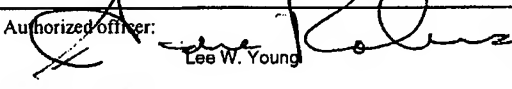
Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer:  Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774
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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 084-06-006	<b>FOR FURTHER ACTION</b> <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. <b>PCT/US 06/33032</b>	International filing date <i>(day/month/year)</i> 24 August 2006 (24.08.2006)	(Earliest) Priority Date <i>(day/month/year)</i> 25 August 2005 (25.08.2005)
Applicant SIBBITT, Wilmer L. Jr.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into \_\_\_\_\_ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

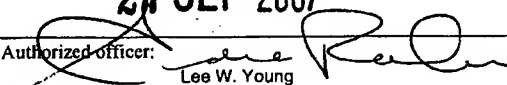
☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 06/33032

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(8): A61B 17/04 (2007.01) USPC: 606/148 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) USPC: 606/148, 149, 150  Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched None  Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) PubWEST (PGPB, USPT, EPAB, JPAB), DialogPRO (Engineering, Patent), Google Scholar Keywords: Tissue eversion, anastomosis, localizing element, guide, fixation, part, element, member, nitinol, memory, sheath, tube, lumen, curve		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---	US 5,976,161 A (KIRSCH et al.) 02 November 1999 (02.11.1999) col 4, ln 4-7, 33-40; col 5, ln 5-43; col 6, ln 66 to col 7, ln 4; col 8, ln 6-20, 30-40; col 10, ln 34-65; Fig 3, 12-15, 19, 27-29.	1-2, 4-8, 10-11, 14-15, 17, 19
Y		3, 9, 12-13, 16, 18, 20
Y	US 5,957,938 A (ZHU et al.) 28 September 1999 (28.09.1999) col 1, ln 59-63; col 2, ln 6-15; col 4, ln 17-21; col 5, ln 12-20; col 7, ln 1 to col 8, ln 11; Fig 1, 4a, 4b, 5, 6.	3, 9, 12-13, 16, 18
Y	US 6,443,963 B1 (BALDWIN et al.) 03 September 2002 (03.09.2002) col 15, ln 36-44; Fig 32.	20
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
* Special categories of cited documents:		
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	
"P" document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search 24 July 2007 (24.07.2007)	Date of mailing of the international search report <b>27 SEP 2007</b>	
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer:  Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774	